

REMARKS

This Office Action Response is submitted in response to the outstanding final Office Action, dated June 26, 2007, as well as the advisory action dated September 14, 2007. Claims 1-3, 17-19, 23-25 and 29 are presently pending in the above-identified patent application. Claims 1, 17 and 23 are herein proposed to be amended. Support for the amendments can be found, for example, on page 7, lines 1-2, page 9, lines 2-11, page 14, lines 24-27, page 9, lines 16-23, page 15, lines 2-6, page 8, lines 15-16 and page 16, lines 4-5. No new matter is being introduced.

In the outstanding Office Action, the Examiner rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112 first paragraph, as allegedly failing to comply with the enablement requirement. Also, the Examiner rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112, the second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The comments of the Examiner in forming the objection and rejections are acknowledged and have been carefully considered.

FORMAL REJECTIONS

As mentioned above, the Examiner rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112 first paragraph, as allegedly failing to comply with the enablement requirement. On page 3 of the Office Action, the Examiner states that

[w]hile it is acknowledged that the specification teaches the SPLASH algorithm, Applicant is arguing that the noted features upon which applicant relies (i.e., phenotype matrix, maximal patterns, submatrices) are not recited in the rejected claim(s).... Therefore, the claims, as written, are not enabled to perform the characterization of gene expression using the steps instantly claimed.

Applicants respectfully assert that independent claims 1, 17 and 23, as amended herein, overcome this rejection by including the limitation of using said one or more transformed phenotype values to determine one or more gene expression patterns by searching said one or more transformed phenotype values for one or more patterns, wherein searching comprises using a pattern-finding algorithm to determine one or more gene expression patterns. Support for this

amendment can be found, for example, on page 9, lines 16-23, page 15, lines 2-6, and page 16, lines 4-5.

Applicants point to, as an example, page 15, lines 2-5, of the specification, wherein it is stated that

5 [o]f all the possible patterns in a phenotype matrix, some of the patterns will be maximal... In step 250, these maximal patterns are determined. There are a variety of well known pattern-finding algorithms and techniques that may be used in this step.

10 Furthermore, Applicants note that on page 9, line 21 of the specification, it is stated that “[t]he maximal patterns may be thought of as gene expression patterns.” (Emphasis added). Consequently, Applicants submit that the limitation of using said transformed gene expression signals to determine one or more gene expression patterns by searching said transformed phenotype values for one or more patterns and using a pattern-finding algorithm to determine
15 one or more gene expression patterns is sufficiently enabled by the specification.

Given the above remarks, Applicants respectfully request reconsideration and withdrawal of the rejections of claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112, first paragraph

Also, the Examiner rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112, the
20 second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. On page 4 of the Office Action, the Examiner states that

25 [c]laims 1, 17, and 23 newly recite, “a plurality of gene expression signals for a gene are determined wherein the signals comprise control data and phenotype data”. It is unclear what makes up the control data versus the phenotype data. Is the control data derived from healthy individuals/cells and the phenotype data derived from unhealthy individuals/cells, for example?

Applicants respectfully assert that on page 6, lines 21-25, the specification describes “an
30 initial set of expression data for one phenotype (generally called the control set and containing information from healthy cells)” and “a set of expression data from another phenotype (generally

called the phenotype set and containing information from unhealthy cells).” Applicants respectfully submit that the above-referenced passage provides sufficient clarification to overcome the rejection.

Also, on page 4 of the Office Action, the Examiner states that

5 [c]laims 1, 17, and 23 recite, “a transforming” step. Since this step has been amended to read “in said control data” it is unclear as to what is intended by this step. Is the transformation ONLY done on the control data?

Applicants respectfully assert claims 1, 17 and 23, as amended, overcome the rejection by
10 including the limitation of transforming said control data, wherein said transforming results in transformed control data having a uniform distribution of said gene expression signals within a selected interval in said control data, and wherein said transformed control data is applied to corresponding phenotype data to convert said corresponding phenotype data to transformed phenotype values. Support for this amendment can be found, for example, on page 9, lines 2-11,
15 as well as on page 14, lines 24-27.

Additionally, on page 4 of the Office Action, the Examiner states that

20 [c]laims 1, 17, and 23, as amended, recite “by searching said transformed gene expression signal for one or more gene expression patterns” to further clarify how the transformed signals are used. It is unclear how to “use” a transformed signal to determine patterns by searching the transformed signals....

Applicants respectfully assert that independent claims 1, 17 and 23, as amended herein, overcome this rejection by including the limitation of using said one or more transformed phenotype values to determine one or more gene expression patterns by searching said one or
25 more transformed phenotype values for one or more patterns, wherein searching comprises using a pattern-finding algorithm to determine one or more gene expression patterns. Support for this amendment can be found, for example, on page 9, lines 16-23, page 15, lines 2-6, and page 16, lines 4-5.

Applicants respectfully assert that the amendments made herein to independent claims 1,
30 17 and 23, in combination with the arguments made above in connection with the 35 U.S.C. §112 first paragraph rejection overcome this rejection.

Also, on page 4 of the Office Action, the Examiner states that

5 [c]laims 1, 17, and 23, as amended, recite “that characterize said control data and said phenotype data to characterize said unknown sample as either said control data or said phenotype data or neither”. It is unclear how the unknown sample can be the control sample or the phenotype sample.... Perhaps it is intended that the unknown sample be more similar to the control versus the phenotype data, for example.

10 Applicants submit that claims 1, 17 and 23, as amended herein, provide sufficient clarification by reciting the limitation of “to classify said unknown sample as similar to either said control data or said phenotype data or neither.” Support for this amendment can be found, for example, on page 7, lines 1-2 of the specification.

15 In view of the foregoing, Applicants submit that all of the pending claims, i.e., claims 1-3, 17-19, 23-25 and 29, are in condition for allowance and such favorable action is earnestly solicited.

If any outstanding issues remain, or if the Examiner has any further suggestions for expediting allowance of this application, the Examiner is invited to contact the undersigned at the telephone number indicated below.

The Examiner’s attention to this matter is appreciated.

20 Respectfully submitted,



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